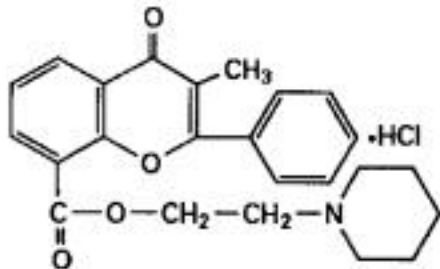


URISPAS - flavoxate hydrochloride tablet, film coated
ORTHO-McNEIL PHARMACEUTICAL, INC.

DESCRIPTION

URISPAS[®] (flavoxate HCl) tablets contain flavoxate hydrochloride, a synthetic urinary tract spasmolytic. Chemically, flavoxate hydrochloride is 2-piperidinoethyl 3-methyl-4-oxo-2-phenyl-4H-1-benzopyran-8-carboxylate hydrochloride. The empirical formula of flavoxate hydrochloride is C₂₄H₂₅NO₄•HCl. The molecular weight is 427.94. The structural formula appears below.



URISPAS[®] is supplied in tablets for oral administration. Each round, white, film-coated URISPAS[®] tablet is debossed with the product name URISPAS[®] and contains flavoxate hydrochloride, 100 mg. Inactive ingredients consist of calcium phosphate, hypromellose, magnesium stearate, polyethylene glycol, starch and talc.

CLINICAL PHARMACOLOGY

Flavoxate hydrochloride counteracts smooth muscle spasm of the urinary tract and exerts its effect directly on the muscle. In a single study of 11 normal male subjects, the time to onset of action was 55 minutes. The peak effect was observed at 112 minutes. 57% of the flavoxate HCl was excreted in the urine within 24 hours.

INDICATIONS AND USAGE

URISPAS[®] (flavoxate HCl) is indicated for symptomatic relief of dysuria, urgency, nocturia, suprapubic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis, urethrocystitis/urethrotigonitis. URISPAS[®] is not indicated for definitive treatment, but is compatible with drugs used for the treatment of urinary tract infections.

CONTRAINDICATIONS

URISPAS[®] (flavoxate HCl) is contraindicated in patients who have any of the following obstructive conditions: pyloric or duodenal obstruction, obstructive intestinal lesions or ileus, achalasia, gastrointestinal hemorrhage and obstructive uropathies of the lower urinary tract.

WARNINGS

URISPAS[®] (flavoxate HCl) should be given cautiously in patients with suspected glaucoma.

PRECAUTIONS

Information for Patients:

Patients should be informed that if drowsiness and blurred vision occur, they should not operate a motor vehicle or machinery or participate in activities where alertness is required.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Mutagenicity studies and long-term studies in animals to determine the carcinogenic potential of URISPAS[®] (flavoxate HCl) have not been performed.

Pregnancy:

Teratogenic Effects-Pregnancy Category B. Reproduction studies have been performed in rats and rabbits at doses up to 34 times the human dose and revealed no evidence of impaired fertility or harm to the fetus due to flavoxate HCl. There are, however, no well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when URISPAS[®] is administered to a nursing woman.

Pediatric Use:

Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS

The following adverse reactions have been observed, but there are not enough data to support an estimate of their frequency.

Gastrointestinal: Nausea, vomiting, dry mouth.

CNS: Vertigo, headache, mental confusion, especially in the elderly, drowsiness, nervousness.

Hematologic: Leukopenia (one case which was reversible upon discontinuation of the drug).

Cardiovascular: Tachycardia and palpitation.

Allergic: Urticaria and other dermatoses, eosinophilia and hyperpyrexia.

Ophthalmic: Increased ocular tension, blurred vision, disturbance in eye accommodation.

Renal: Dysuria.

OVERDOSAGE

The oral LD₅₀ for flavoxate HCl in rats is 4273 mg/kg. The oral LD₅₀ for flavoxate HCl in mice is 1837 mg/kg.

It is not known whether flavoxate HCl is dialyzable.

DOSAGE AND ADMINISTRATION**Adults and children over 12 years of age:**

One or two 100 mg tablets 3 or 4 times a day. With improvement of symptoms, the dose may be reduced. This drug cannot be recommended for infants and children under 12 years of age because safety and efficacy have not been demonstrated in this age group.

HOW SUPPLIED

URISPAS[®] (flavoxate HCl), 100 mg, is supplied as round, white, film-coated tablets, debossed with the product name URISPAS[®] in bottles of 100.

100 mg 100's: NDC 17314-9220-1

Store between 15° and 30°C (59° and 86°F).

Rx only

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